Minutes for 2/10/11 Stakeholder Meeting

ACTION ITEMS ARE IN BOLD

Comments on the minutes – e-mail any comments to Carol.

Corrections on subcommittee minutes – none

Will not move forward on fee reg. No one to back fee reg at State House. DHEC will not pursue it, must come from regulated community. Budget looking a little better.

As we have stakeholders together, can talk about a different way to restructure that and come up with a better way to generate revenue. **Let Carol know if people want to get together to discuss changes to fee reg.**

Definitions subcommittee report:

Went through old reg, different state regs, EPA, etc. to find definitions. Came up with list of definitions. Some need more discussion, some may be removed, few others that subcommittees might have more specific definitions.

Definitions reviewed and discussed during meeting:
Laboratory – **more specific on "a place"** e.g., location, facility, field lab. Have fixed labs, mobile labs, "pickup truck" or uncontrolled environment

Need to define field laboratory
Have lab as a category and define the different types
Needs to go to Field Parameter Subcommittee
Would each truck be a field parameter lab?
If there is an interest in field parameters – need to put a person on that subcommittee

Definition of a field parameter lab is very contentious issue. UST program would very much like this defined due to QAPP.

Reporting limits – data reporting subcommittee will also come up with definition

Chain-of-custody – chain-of-custody subcommittee will address

DOC – quality assurance subcommittee will need to address – will be added to list of things to address

Initial Calibration – add this to QA subcommittee

Have 12 essential QC items listed in Federal Register – will need to define

Everyone needs to look over list to see if there are any questions or additional terms that need to be added. Terms in red – are these terms we would need to have in reg?

Question about why we need to define "commercial laboratory" – certification program based on commercial, field, municipal, mobile, industrial, etc.

Interim approval – we do not have interim approval, lab cert has always looked at it as either certified or not certified. If there was interim approval, would have to define it. If there is provisional/interim certification would somehow have to qualify data. Could see some need for interim approval for larger labs. National program is having hard time doing on-sites every year, NC is way behind, problem for certification because our reg requires every 3 years. IL is no longer going out of state. SC has been able to keep up with our on-site eval.

Everyone in agreement to remove interim approval for definitions.

<u>Personnel Qualifications and Training Records</u>

Ensure competency of staff
Define who is responsible, how to you define laboratory director, decertification
Define qualifications, add education requirements
Discuss potential guidance documents
How do we begin to write this, what will the document look like?

Wisconsin regulation – breaks out drinking water and puts that in reg, e.g. labs doing DW have to meet requirements in DW manual, other labs have other qualifications defined. Something to consider for SC reg.

Concerns about people being excluded due to education/experience requirements?

- Don't exclude people with less education, if they have experience.
- More of a business decision instead of certification issue?
- Every person in the state should have the qualifications, education, license required
- Certification doesn't certify analysts, get into LLR, would like to see licensing for laboratory analysts. Outside of this reg's scope.
- Don't believe state should put education requirements on analysts.
- LLR requires an exam be passed to get licensed.
- Employers should be required to keep training records.
- Be careful how stringent we get in reg., balance between training, education requirements, and experience.
- Should be able to hire and train people as labs need to.
- Don't glaze over training, need to have formal structure on how you train people. When writing reg, need to write it so it forces people to create this formal structure.
- Have some structure, and guidance, but have it uniform across all laboratories.
- Needs to be uniform across all laboratories so the process is known.

Need to develop more guides in the type of training needed for analysts. As a laboratory, need to have something written down in regards to education and experience and training in QA plan.

Would like to see more accountability and responsibility in the laboratories. How do we make that person accountable? How much control should a company have vs. DHEC?

Have to find a balance between on the job training, degree, experience so that people aren't being excluded.

Licensure with reg, if we were to write that in, State House would probably shoot it down due to the financial implications/impacts. Talking about a whole new program if we put this in reg. There isn't anyone to take this on. Would it go through LLR? Would have to be developed, would have to be a joint effort. SCDHEC Lab Cert program cannot take this on.

Don't need to discuss analyst qualifications. Can put in reg requirements for laboratories to implement training program.

Data qualification discussion – holding times, contract labs, qualified data, communication between commercial labs

Quality Systems/QA/QC Subcommittee

Decided to use TNI standard as basis. Will be a long process, not sure if this format will be kept. Looked at other state regulations. Biggest issue is to find a way to make the Quality Systems document apply to all types of laboratories. Will try to tackle the chemistry and micro modules.

Main points discussed in subcommittee meeting:

- Remove ISO language
- Remove TNI from language
- Went over in detail changing accreditation to certification
- Discussed definition of sample batch, **will need definitions for these**
- Chain-of-custody terminology will go through CoC Subcommittee
- Change deficiencies to findings
- Discussed use of LOQ and LOD, will MDLs be required, will we use LOD and LOQ for all methods?
- Responsibilities for lab director, what if lab director is out – tabled discussion
- Discussed requirements for data integrity
- Discussion of SOP requirements, changes
- Looking at content of TNI standard more than structure
- Document Control – need to find a way to make this work for smaller labs
- Corrective action – identify root cause
- Control of records – how long to keep, keep it general, or include language from regulations, access to archived information
- **Essential quality control definitions – must address this!**
- Possibility of having guidance document.
- Homework – will look at other state regs.
- Started with TNI and plan to work back from that to include smaller labs, may go back and approach in a different way to break it down to usable format.
- Deleted a lot out that was not applicable

If there is anyone in a smaller lab that wants to be a part – please send in volunteer information

Comments:

- Look carefully at how you define or require LOD/LOQ vs. MDL – federal regulations
- Have to decide if we are going to have separate requirements for different labs
- Define QC terms pertaining to what is applicable, instrumentation, technology, etc.
- Are we going to require something different between commercial vs. field, etc?
- Look at those essential QC items compared to the types of labs.

Data Reporting Subcommittee

Things discussed in subcommittee meeting:

- need someone from state lab

- elements that need to go into regulation – will look at other regs to see that they have in them (homework)
- reporting limits vs. detection limits – define reporting limit and detection limit, differences between the two, how can we state it in the reg to define it to the end user – would require standardizing the terminology
- Reference reporting limits to other regulations (PQL) have everyone report the same think. Decided laboratories needed to report both RL and DL.
- LOD/LOQ, MDL, MCL, etc.
- From regulatory perspective – see disconnect between lab and middle man to agency – goal would be to report the same thing and consultant would not have as much play with data.
- What are the critical items to include on the data reports?
- Define qualifiers, at least a few, to define what would need to be used in data
- Format of reports for end users e.g. ND, < RL, terminology
- Different labs might have different requirements – whether or not data generation is for internal use vs. commercial laboratory providing data to end user.
- Subcontract lab work – how is it incorporated into data reports to end user.

Comments:

- How is MDL being used? MDLs change every time you do something. Would have to change this in LIMS continually. Reporting MDL creates work.
- Trying to state that there is a difference between the MDL and RL. Some people reporting MDL and calling it RL.
- Gives regulatory agency more information if something shows up below the RL, but above the MDL
- **May need to look at TNI standard as far as reporting.**
- If we require them to report both, it would require them to at least report that reporting limit.
- Have PQLs established for WW
- BOW would like to see both RL and MDL because there may be a value reported as J flag that would be used to evaluate trends in sites/samples
- **Define terminology using definitions subgroup, need to give definitions group list of terms.**
- Hard to commit to adding MDLs to reports due to budget cuts and staff restraints
- If labs do provide MDL and RL, then you have to do both. Otherwise must have RL
- **If the lab provides the MDL on the report, then the RL must be on there. Otherwise must have RL.**
- LOD verification could be useful to verify MDL
- If using MDLs, have to define the way MDLs are done. Must standardize MDL process.
- **Will need to define items that have to be on report e.g. date, time, analyst, method reference, etc.**
- Would like to cut down on qualifiers
- Needs to be communication between labs and clients.
- What about samples analyzed out of holding times? Do you report with qualifier, not report at all?
- What kind of requirements do you put into place for subcontracted work?
- One problem – subcontract a bunch of client's samples together – separate out?
- Should be accountability, should not be able to put another lab's data into report and sign off on it.
- Responsibility needs to fall with client – need to establish requirements in report.
- **Need to give some framework to make data usable by end user – add structure to the process**
- Needs to be defined in reg how data should be reported.
- Certification does not say all data produced is good. Cannot look at all data.
- Going to come down to lowest bidder

- Each end user has to submit the quality objectives, as a contract laboratory they must provide what end user has asked for. Up to end user to define what data is needed. Not up to lab cert to define what is needed.
- **Define end user and end user defines what needs to be reported**
- NC makes Pace Huntersville fill out a form whenever a sample is out of compliance and send it to NC.

Sample Chain of Custody

Definition of chain of custody. Evidentiary chain of custody – some discussion on this. Not going to require in reg, but mention it. **Add these definitions to definitions subcommittee.**

Sample acceptance policy. Discussion on some wastewater samples that have to be reported, can labs reject samples? Shouldn't report any samples that have not been analyzed correctly.

Sampling handling protocol.

Sample preservation and holding time. Discussion about Blue Ice – should this be addressed, taken out, etc.?

Do we need to tie ourselves down in the reg about specific temp requirements for preservation? Refer to regs, take out.

Quality systems will be addressing preservative traceability.

Take out WET section D. temp requirement.

Keep sample container on chain? Traceability of sample containers. Discussion on why sample containers are necessary on CofC.

Specify collection date and time for each sample collected at each site.

#9 on section 4.A. need to reword
#7 add temperature as requirement for composite sampler when sample is composited.

Look at rest of write-up for sample collection and send comments

Field Parameter Subcommittee

Defining field parameter lab vs. laboratory. How to define field parameter. Field parameters definition should include info for holding time of 15 minutes. Maybe include examples e.g. includes but not limited to…

How do you identify a field lab? TNI standard has a definition. State of Virginia has definitions. DW manual specifies controlled environment. Where does instrumentation have to be calibrated and stored? Storage of pH buffers and reagents? Does the individual buffer that is taken into the field, or larger bulk solution? What defines fresh buffer?

Definition of a day? 24 hour period? Depends on how you define a day? Work shift? **Definitions subcommittee needs to define a day.**

Where does accountability lie with operators out in field? Have a QA person to review data? Training documentation?

Will have to be a structure or facility to define as a field lab. Equipment to be taken out. Where do you calibrate?

Consultants and groundwater samplers do not have certification – complaint from certified lab – feels contractors need to have certification and any other determinations being made in the field. Losing business because people are allowed to do analyses without being certified.

If you are going out of town – off site for a few days, have to take meters and buffers with you. How do you handle this?

Must be oversight if we allow for field calibration. Some people are really honest, others are not.

Spell out who can use certification number? Use personnel list. Who is working for laboratory? Some have contractors – how do you treat that?

Is there a documentation requirement that can be put into place to get some level of accountability?

Contractors will rent equipment for a day – won't calibrate the meter b/c they expect it to be calibrated when they get it. Tightening up requirements on field calibration.

Discussed other field data, field GC, screening, etc. Big issue with field screening is calibration.

Need to table discussion and address a little more with BLWM.
Get any comments to Heather

Next meeting scheduled for March 31st.

Name	Company
Pat Walker	SCDHEC
Connie Gibson	SCDHEC
Cynde Devlin	SCDHEC
Crystal Rippy	SCDHEC
Nydia Burdick	SCDHEC
Judy Graham	SCDHEC
Chris Doll	SCDHEC
Sandra Fleming	SCDHEC
Alfred Baquiran	SCDHEC
Leigh Plummer	SCDHEC
Susan Butts	SCDHEC
Micheal Mattocks	SCDHEC
Mahtab Gowan	SCDHEC
Jamie Berry	SCDHEC
Bennie Cockerel	SCDHEC
Heather Beard	Richland County

Thomasena Simmons	BP Cooper River
Jason Collins	Keowee Key Utility Systems
Jeff Czarnecki	Greenville Water System
Allan Clum	MPW
Cheryl Johnson	Pace
Marleen Gillespie	Giant Resource Recovery